JAN 2 5 2006

K052812

510(k) Summary of Safety and Effectiveness

Applicant Name and Address: Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Contact Person: Peggy Hansen, RAC
Director, Clinical, Regulatory, and Quality Assurance
Tel: (201) 405-1477
Fax: (201) 405-1355

Date of Summary: December 21, 2005

Device Common Name: Bone Grafting Material
Bone Void Filler

Device Trade Name: OssiMend™ Bone Graft Material

Device Classification Name: Filler, Bone Void, Calcium Compound
Regulation Number: 888.3045
Device Class: Class II
Product Code: MQV

Predicate Device(s): HEALOS® Bone Graft Material, K012751
CopiOs™ Bone Void Filler, K033679
Collagraft Strip Bone Graft Matrix, K000122
Vitoss® Scaffold Foam Bone Graft Material, K032288
ORTHOSS™ Resorbable Bone Void Filler, K014289
OsteoGuide® Anorganic Bone Mineral Products, K043034

Description of the Device

OssiMend™ Bone Graft Material (OssiMend) is a collagen mineral composite matrix processed into strips, pads, or granular form for surgical implantation. The principle components of OssiMend are bovine type I collagen and anorganic bovine bone mineral. The mineral particles are dispersed within collagen fibers forming a three-dimensional open porous matrix consisting of 55% bone mineral and 45% collagen. OssiMend is provided as a sterile, dry material that is hydrated with autogenous bone marrow at the point of use. OssiMend strips and pads can be cut into shapes and are designed to retain their shape and physical integrity following implantation into a bony site, while the granular form can be molded to fit the bone defect. OssiMend is fully resorbed during the natural process of bone formation and remodeling.

Intended Use

OssiMend, combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

Summary/Comparison of Technical Characteristics

OssiMend and its predicates have the same technological characteristics. In particular, OssiMend and their predicates are the same with respect to intended use, design, materials, material characterization, form, and sizes.

Safety

OssiMend has been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all selected FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Effectiveness

The characteristics of the OssiMend meet the design requirements for an effective bone grafting material, and an animal study confirmed the effectiveness of the product for use as a bone void filler.

Conclusion

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, and an animal study show that OssiMend Bone Graft Material is safe and substantially equivalent to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2006

Ms. Peggy Hansen, RAC
Director, Clinical, Regulatory, and Quality Assurance
Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K052812/S1
Trade/Device Name: OssiMend™ Bone Graft Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: December 22, 2005
Received: December 23, 2005

Dear Ms. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052812

Device Name: OssiMend™ Bone Graft Material

Indications for Use:

OssiMend, combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052812